REMARKS

The Office Action mailed July 26, 2006 has been received and reviewed. Claims 1, 2, and 5-23 are pending herein. Claims 3 and 4 have been canceled herein. Claims 1 and 2 have been amended herein. Claims 6-22 are withdrawn as being drawn to a non-elected invention. New claim 23 has been entered herein. The application is to be amended as previously set forth. All amendments and claim cancellations are made without prejudice or disclaimer. No new matter has been entered. Claims 1-5 stand rejected. Reconsideration is respectfully requested.

1. claim rejections 35 U.S.C. § 112

1.1 Claims 1-5 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement, for reciting derivatives or functional analogues of EPO. Claims 3 and 4 are cancelled herewith, rendering the rejection moot as to them. Although applicants respectfully disagree with the Examiner, to speed up prosecution claim 1 has been amended to remove the recitation of "or a derivative or functional analogue thereof," rendering the rejection moot.

1.2 Claims 1-5 stand rejected under 35 U.S.C. § 112, first paragraph, because allegedly the specification is enabling for treatment but not for prevention. Claims 3 and 4 are cancelled herewith, rendering the rejection moot as to them. Although applicants respectfully disagree with the Examiner, to speed up prosecution claim 1 has been amended to remove the language regarding methods of prevention. Applicants welcome the Examiner's conclusion that the specification is enabled for treatment, and conclude that the removal of methods for prevention from the claim language thus renders the rejection moot.

1.3 Claims 1-5 stand rejected under 35 U.S.C. § 112, second paragraph. Claims 3 and 4 are cancelled herewith, rendering the rejection moot as to them. In claim 1, the recitation "E1A" has been spelled out on first occurrence, which should overcome the rejection as to this part. For claim 2, the recitation "PER.C6" has been removed from the claim and replaced by reference to ECACC deposit no. 96022940 for the cells, which should overcome the rejection. Support for the amendment may be found in the copy of the deposit receipt filed with the application and in

paragraph [0017] of the specification as amended in the preliminary amendment filed on the same day as the application. The ECACC has been established as a recognized IDA Patent Depository since 1984 under the Budapest Treaty (1977). It accepts cell lines, viruses, bacteria, and DNA for deposit. As such, a deposit has made under the terms of the Budapest Treaty.

2. claim rejections 35 U.S.C. § 103

Claims 1-5 stand rejected under 35 U.S.C. § 103 as being allegedly unpatentable over Brines *et al.* (US 6,531,121) in view of Berg *et al.* (US 5,506,118). Claims 3 and 4 are cancelled herewith, rendering the rejection moot as to them. Applicants further respectfully disagree for at least the following reasons.

2.1 The claims as amended refer to chronic heart failure. Support for the amendment may be found throughout the as-filed specification, such as at page 2, lines 26-31. Brines does not relate to chronic heart failure (the term 'chronic heart failure' or 'chronic cardiac failure' is not found in Brines). Further, Brines contains no motivation or suggestion to be combined with or modified by Berg.

2.2 Berg relates to a combination of a poly-GT element with an immediate early gene product of a large DNA virus, such as adenovirus E1A, to increase transcription. Berg thus does not teach that E1A is used in each and every cell and in all circumstances to enhance expression activity, but only in particular circumstances (*i.e.* with a poly-GT element). Berg does not relate to EPO expression (the term 'EPO' or 'erythropoietin' is not mentioned in Berg). Thus, Berg contains no motivation or suggestion to be combined with or to modify Brines.

2.3 The present application discloses an advantage for using EPO that has been produced in E1A-expressing cells for treating chronic heart failure, in that such EPO causes less of a side effect (increase in hematocrit values) than commercial EPO preparations (*cf.* paragraphs [0008] and [0022]). This benefit is especially useful in a chronic setting as claimed, and relates to different glycosylation of EPO when produced in E1A expressing cells, which is not disclosed in either Brines or Berg, and thus could not be foreseen based on these references.

2.4 Thus, there is no rationale to combine Brines with Berg, and even if these references could be combined (which as done by the Examiner applicants respectfully believe is merely based on hindsight) this does not result in a combination wherein all claim elements are met. Hence, the invention as claimed is not obvious over the cited references.

2.5 The reasoning above also applies to new claim 23.

2.6 The reasoning above applies *a fortiori* for the subject matter of claims 2 and 5: Berg does not mention PER.C6 cells, and Brines is silent about patients with chronic heart failure that are not anemic.

2.7 Applicants thus believe that at least for these reasons the claims are not obvious over the cited art. Reconsideration is respectfully requested.

If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

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